REMARKS

Claims 19 to 33 are pending in this application. Claims 19 to 33 are rejected as follows:

(1) claims 19 to 33 are rejected under 35 U.S.C. §112, second paragraph;

(2) claims 19 to 33 are rejected under 35 U.S.C. §112, first paragraph; and

(3) claims 19 to 33 are rejected under the judicially-created doctrine of obviousness-type double patenting.

Applicants are herein amending the specification to update the Cross-Reference to Related Applications.

Rejection under 35 U.S.C. § 112, second paragraph

In the Office Action, claims 19 to 33 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for using the terms "eating disorders" and "sexual dysfunction" because each term encompasses conditions that are seemingly opposing. Applicants respectfully traverse the rejection because there is nothing unclear about what conditions applicants intend to claim in their method claims -- *inter alia*, eating disorders (such as anorexia nervosa and bulimia nervosa) and sexual dysfunction (including premature ejaculation) (page 10, lines 31 to 33). Those skilled in the art would have no difficulty understanding what conditions are encompassed by these two terms and, as such, the terms are definite. Applicants believe that the Office Action is not challenging the definiteness of the terms under 35 U.S.C. § 112, second paragraph, but actually whether methods of treating these conditions with the compounds of the invention are enabled under 35 U.S.C. § 112, first paragraph, which is addressed below. Accordingly, applicants request withdrawal of the rejection of claims 19 to 33 under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 112, first paragraph

In the Office Action, claims 19 to 33 are rejected under 35 U.S.C. § 112, first paragraph as allegedly being non-enabled, specifically with methods of treating obesity,

eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction, and sexual dysfunction. Applicants respectfully traverse the rejection because the specification enables a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and to use the invention commensurate in scope with claims 19 to 33.

In order to establish a *prima facie* case of non-enablement, the following must be established by the Patent Office:

1. a rational basis as to
   a. why the disclosure does not teach; or
   b. why to doubt the objective truth of the statements in the disclosure that purport to teach;
2. the manner and process of making and using the invention
3. that correspond in scope to the claimed invention
4. to one of ordinary skill in the pertinent technology,
5. without undue experimentation, and
6. dealing with subject matter that would not already be known to the skilled person as of the filing date of the application.

Any rejection under 35 U.S.C. § 112, second paragraph, for lack of enablement, must include evidence supporting each of these elements. Applicants respectfully submit that the Office has failed to meet its burden of establishing a *prima facie* case of non-enablement.

It has been consistently held that the first paragraph of 35 U.S.C. § 112 requires nothing more than *objective* enablement. Furthermore, a specification that teaches how to make and use the invention in terms which correspond in scope to the claims *must* be taken as complying with the firs paragraph of 35 U.S.C. § 112, *unless* there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Stahelin v. Secher*, 24 U.S.P.Q.2d 1513, 1516 (B.P.A.I. 1992) (citing *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (C.C.P.A. 1971). "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to ... back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). In the instant application, no evidence has been provided

of why the disclosure is insufficient or why the Office does not believe the statements contained therein. Accordingly, applicants respectfully submit that the Office has not met its burden.

It appears that the Office is challenging the objective truth of the use of the compounds to treat the various conditions, and, in particular, the nexus between 5-HT_{1A} receptor ligands and the treatment of obesity, eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction, and sexual dysfunction. Applicants have provided procedures for the assay to determine the affinity for the 5-HT transporter, the assay for the 5-HT_{1A} receptor, and the assay for the antagonist activity at 5-HT_{1A} receptor of the compounds useful in the methods of the invention in the specification on page 9, line 19 to page 10, line 11. Applicants have also provided data on page 10, lines 13 to 24 to show that representative compounds of the invention are combined serotonin reuptake inhibitors (SSRI) and 5-HT_{1A} antagonists. As such, they are useful for the treatment of diseases commonly treated with the *administration of SSRI antidepressants*, including obesity, eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction, and sexual dysfunction. This nexus is recognized in the art. See, for example, US-B-6,169,098 [showing 5-HT_{1A} receptor antagonists are useful in the treatment of eating disorders (obesity, anorexia, bulimia), sexual disturbances, alcoholism, and thermoregulatory disorders (column 4, lines 24 to 32)]; Lee, *et al., Formulary* 2002; 37: 312-319 (showing use of SSRIs in treatment of alcohol dependence; eating disorders including bulimia nervosa, anorexia nervosa, and binge-eating disorders; and sexual dysfunction]; Stone, *et al., Am. Fam. Physician* 2003; 68: 498-504 (describing use in the treatment of premature ejaculation); WO 00/34263 (describing use antagonist of $5HT_{1A}$ receptor, *inter alia*, in the treatment of alcohol abuse). Each of these documents is enclosed.

A lack of working examples with respect to methods of treating obesity, eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction, and sexual dysfunction does not automatically make a patent non-enabling. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984). Additionally, 35 U.S.C. § 112 does not demand a "working example," and an application cannot be fatally defective merely because it lacks one. *In re Long*, 151 U.S.P.Q. 640 (C.C.P.A. 1966); *In re Honn et al.*, 150 U.S.P.Q.

652 (C.C.P.A. 1966); *In re Bartholome et al.*, 156 U.S.P.Q. 20 (C.C.P.A. 1967); and *Ex parte Kenega*, 189 U.S.P.Q. 62 (Pat. Off. Bd. App. 1974).

Because there is a nexus between compounds having serotonin reuptake inhibitory (SSRI) and 5-HT_{1A} antagonist activity and methods of treating obesity, eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction, and sexual dysfunction, applicants respectfully submit that there is not a reasonable basis for rejecting the claims. Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 112, first paragraph.

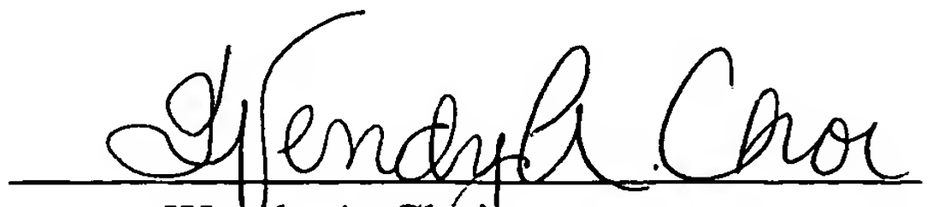
Obviousness-Type Double Patenting Rejection

Claims 19 to 33 are rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 14 to 17 of US-B-6,656,950. While applicants are not conceding that claims 19 to 33 of the subject application are obvious over claims 14 to 17 of US-B-6,656,950, applicants are submitting herewith a terminal disclaimer over US-B-6,656,950 to obviate the rejection. Accordingly, applicants request withdrawal of the rejection of claims 19 to 33 under the judicially-created doctrine of obviousness-type double patenting.

Conclusions

Applicants respectfully request reconsideration and withdrawal of the rejection of the claims in view of the remarks. If the Examiner has any questions, the Examiner is invited to call the undersigned at (215) 557-3861.

Date: June 22, 2004



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